

U.S. DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAKE CHARLES DIVISION

US v Seth Fishman,
20-cr-160-MKV

B

Motion for Bill of Particulars

UNITED STATES OF AMERICA

VERSUS

KYLE JAMES HEBERT, DVM;
KOHLL'S PHARMACY &
HOMECARE, INC., d/b/a
ESSENTIAL PHARMACY
COMPOUNDING

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NO. _____
18 U.S.C. § 371
21 U.S.C. §§ 331(a), 333 (a)(2)
21 U.S.C. §§ 331(c), 333 (a)(2)
21 U.S.C. §§ 331(k), 333 (a)(2)

2:17-CR-00039
JUDGE MINALDI
MAGISTRATE JUDGE KAY

INDICTMENT

THE GRAND JURY CHARGES:

COUNT 1
Conspiracy
[18 U.S.C. § 371]

A. At all relevant times:

1. The defendant, Kyle James Hebert, was a doctor of veterinary medicine licensed to practice in the State of Louisiana and was licensed by the Louisiana State Racing Commission to practice veterinary medicine at horse racing tracks in the state of Louisiana. Hebert owned Southern Equine Sports Medicine ("SESM"), which operated veterinary clinics in Lake Charles, Louisiana and Sunset, Louisiana that specialized in the treatment of horses, including racehorses. Both of those clinics were located near horseracing tracks.

2. The defendant, Kohll's Pharmacy & Healthcare, Inc., (Kohll's) was a Nebraska registered corporation located in Omaha, Nebraska, primarily engaged in the retail business of selling prescription drugs and other merchandise. Kohll's conducted business under the trade name Essential Pharmacy Compounding (EPC). EPC was advertised as a compounding pharmacy engaged in the business of selling compounded drugs, including dermorphin, to licensed veterinarians and others in interstate commerce, and operated as a subdivision of Kohll's, and sometimes identified itself on its drug product labels as EPC. (hereinafter referred to as Kohll's d/b/a Essential Pharmacy Compounding).

3. The Louisiana State Racing Commission ("Racing Commission") was an entity created by the Louisiana legislature and domiciled in New Orleans, Louisiana. The Racing Commission was charged with regulating the horseracing industry in Louisiana in order to guarantee its honesty and safety, and to safeguard it from corrupt, dishonest, or unprincipled practices. One of the ways the Racing Commission sought to accomplish those goals was to ensure that no one responsible for the custody of a competing horse had administered, or allowed to be administered, any prescribed medication to the horse within a specified time prior to the race; nor administered, or allowed to be administered, any illegal substance to the horse at any time. The Racing Commission was authorized by the Louisiana Legislature to promulgate rules and regulations governing the operation of all horse races, race tracks, and race meets, held in Louisiana and to conduct investigations and enforce state laws and regulations pertaining to horse racing.

4. Under Louisiana state law, the administration of any drug to a racing horse was governed by the rules and regulations adopted by the Louisiana State Racing Commission. La. R.S. 4: 175.

5. Under the rules and regulations promulgated and adopted by the Louisiana State Racing Commission governing horse racing:

- a. Providing a racing horse any substance or material for human or animal use, ingestion or injection, or for testing purposes that was not formally approved by the United States Food and Drug Administration was prohibited. Title 35, Louisiana Administrative Code, Section 1707.
- b. No one other than a licensed veterinarian was allowed to have a needle or syringe of any kind or type or description on his person or in his custody, control or possession or in the custody, control, or in the possession of any of his employees while on any racing premises. Title 35, Louisiana Administrative Code, Section 1315.
- c. No medication other than a bleeder or nonsteroidal and/or anti-inflammatory medication was allowed to be administered within 24 hours of a race in which a horse is entered to race. Title 35, Louisiana Administrative Code, Section 1505 A.
- d. Only a licensed veterinarian was allowed to dispense and administer bleeder medication and no horse entered to race was allowed to be administered bleeder medication within 4 hours of post-time of the race in which the horse was to run. Title 35, Louisiana Administrative Code, Section 1507.

- e. The possession of any prohibited drugs, hypodermic syringes, hypodermic needles, or similar instruments that may be used for injection by anyone other than a licensed veterinarian was prohibited within the confines of a race track or within its stables, buildings, sheds or grounds, or within an auxiliary (off-track) stable area, where horses were lodged or kept, which horses were eligible to race over a race track of any association holding a race meeting. Title 35, Louisiana Administrative Code, Section 1743.
 - f. The use of a stimulant, depressant, or anesthetic in a manner that might affect, or tend to affect, the racing performance of a horse was prohibited. Title 35, Louisiana Administrative Code, Section 1717.
6. The Louisiana State Police had jurisdiction to enforce state law and to investigate suspected violations of state law and the rules and regulations governing horse racing.
7. The United States Food and Drug Administration ("FDA") was an agency of the United States of America operating under the authority of the United States Department of Health and Human Services. The FDA was the agency responsible for enforcing the provisions of the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. § 301, *et seq.* Among other duties, the FDA was responsible for protecting the health and safety of the American public by ensuring, among other things, that drug products intended for use in animals (hereafter referred to as "animal drugs") had been demonstrated by scientifically valid methods to be safe and effective for

their intended uses, and bore the kind of labeling that would ensure their safe and effective use.

A. Under the federal Food, Drug and Cosmetic Act (FDCA):

- a. "Drugs" were defined as, among other things, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; articles (other than food) intended to affect the structure or function of the body of man or other animals; and articles intended for use as a component of any drug. 21 U.S.C. § 321(g)(1)(B), (C) & (D).
- b. Some drugs intended for use by animals other than man, because of their toxicity or other possible harmful effects, the method of their use, or the collateral measures necessary to their use, were not safe for use except under the professional supervision of a licensed veterinarian. These drugs were commonly known as "prescription animal drugs." 21 U.S.C. § 353(f)(1).
- c. Prescription animal drugs could only be legally dispensed by or upon the lawful oral or written order of a licensed veterinarian in the course of the veterinarian's professional practice. An order was lawful if it was a prescription or order otherwise authorized by law, and if an oral order, promptly reduced to writing by the person filling the order and filed by that person.

- d. A drug was misbranded if, among other things:
 - i. its labeling was false or misleading in any particular (21 U.S.C. § 352(a)); or
 - ii. any words, statements, and other information required by or under authority of the FDCA to appear on the labeling were not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use (21 U.S.C. § 352(c));
- e. A drug was also misbranded if the labeling on the drug did not bear adequate directions for use (21 U.S.C. § 352(f)(1)). “Adequate directions for use” meant directions under which a layman could use a drug safely and for the purposes for which it was intended without a licensed practitioner's supervision. Directions for use could be inadequate because of omission, in whole or in part, of:
 - i. Statements of all conditions, purposes, or uses for which such drug was intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug is commonly used;
 - ii. quantity of dose; or
 - iii. frequency of administration or application.

- f. Animal drugs were required to be labeled as to their source, nature and appropriate uses, and the failure to include required information on the labeling was misbranding. 21 U.S.C. § 352 (b) and (f).
 - g. A new animal drug is deemed adulterated under the FDCA with respect to any particular intended use of such drug unless there is in effect FDA approval of an application filed with respect to such use or intended use. 21 U.S.C. §§ 351(a)(5) and 360b (a)(1).
 - h. The act of dispensing a prescription animal drug without a lawful written or oral order of a licensed veterinarian was deemed an act which resulted in the drug being misbranded while held for sale. 21 U.S.C. § 353(f)(1)(C).
- B. The FDCA prohibited the doing or causing of any of the following:
 - a. The introduction and causing the introduction in interstate commerce of any adulterated or misbranded drug (21 U.S.C. § 331(a));
 - b. The receipt or causing the receipt in interstate commerce of any adulterated or misbranded drug, and the delivery or proffered delivery thereof for pay or otherwise (21 U.S.C. § 331(c)); and
 - c. The doing of any act with respect to a drug, if such act was done while the article was held for sale (whether or not the first sale) after shipment in interstate commerce, and resulted in the drug being adulterated or misbranded. 21 U.S.C. § 331(k).
- C. Dermorphin was a hepta-peptide and natural opioid about 30 times more potent than morphine. Dermorphin is naturally secreted by a

species of tree frog native to South America. Dermorphin has been synthesized by compounding pharmacies in the United States, primarily for its illegal use in horse racing based on the belief that horses treated with dermorphin may run harder than they would otherwise because the horses may not be aware they are injured.

- D. There was no drug containing dermorphin approved by FDA for legal use in humans or animals in the United States.

THE CONSPIRACY

B. From on or about November 11, 2010, and continuing until an unknown date during the month of December 2012, in the Western District of Louisiana and elsewhere, the defendants, Kyle James Hebert, DVM, and Kohll's d/b/a Essential Pharmacy Compounding, and others both known and unknown to the grand jury, knowingly, willfully, and unlawfully combined, confederated, conspired, and agreed together to commit offenses against the United States to wit: to introduce and deliver a prescription animal drug in interstate commerce, namely, dermorphin, which was adulterated as defined at 21 U.S.C. §§ 351(a)(5) and 360b, and misbranded as defined at 21 U.S.C. § 352(a), (c) and (f)(1), and to deliver and proffer the delivery thereof for pay and otherwise; and to dispense a prescription animal drug, namely dermorphin, after the drug had traveled in interstate commerce, without a lawful written or oral order of a licensed veterinarian, acts which resulted in the drug being misbranded while held for sale, all with the intent to defraud and mislead the United States Food and Drug Administration of its regulatory authority over animal drugs, the Louisiana Racing Commission of its regulatory authority over horse racing, and the Louisiana

State Police of its law enforcement authority over matters involving horseracing, in violation of Title 21, United States Code, Sections 331(a), 331(c), 331(k), and 333(a)(2).

THE OBJECTS OF THE CONSPIRACY

C. It was an object of the conspiracy to obtain a synthetic version of dermorphin, which could be misleadingly labeled and delivered for pay and otherwise to persons to administer to horses in violation of state and federal law for the purpose of influencing the outcome of horse races, including horse races at racetracks within the Western District of Louisiana.

It was further an object of the conspiracy to conceal this activity by creating and causing to be created false billing records, invoices, and other documents that might otherwise reveal that the acts of distributing an unapproved, adulterated, and misbranded drug for use in horses.

MANNER AND MEANS OF THE CONSPIRACY

D. The manner and means by which the defendants, Kyle James Hebert, DVM, and Kohll's, d/b/a Essential Pharmacy Compounding, sought to accomplish the objects of the conspiracy included the following:

1. It was part of the conspiracy that the defendant, Kohll's d/b/a Essential Pharmacy Compounding, obtained synthetic dermorphin from a chemical supply company in Torrence, CA, and offered that product for sale as an animal drug.

2. Defendant, Kohll's, d/b/a Essential Pharmacy Compounding, falsely relabeled the product received from Torrence, CA with labeling that made it appear that the product was a compounded drug created by Kohll's, d/b/a Essential Pharmacy

Compounding, for a specific horse owned by a specific person upon the prescription of defendant, Kyle James Hebert, DVM.

3. It was further part of the conspiracy that between November 11, 2010, and May 2, 2012, the defendant, Kyle James Hebert, DVM, purchased approximately 815 milligrams of dermorphin at a cost of approximately \$25,140 from defendant, Kohll's, d/b/a Essential Pharmacy Compounding. Between December 2010, and November 2011, invoices issued by defendant, Kohll's, d/b/a Essential Pharmacy Compounding, for dermorphin falsely identified the drug using the fictitious name, "d-peptide." Thereafter, defendant, Kohll's, d/b/a Essential Pharmacy Compounding, issued invoices describing the drug as dermorphin, but used the same product inventory on its invoices and vials as it had with the drug when it was labeled d-peptide, and with respect to sales of dermorphin to defendant, Kyle James Hebert, DVM, the equine patient information remained the same for all of the dermorphin sold to defendant, Kyle James Hebert, DVM, regardless of the name in the description on the invoice.

4. It was further part of the conspiracy that defendant, Kyle James Hebert, DVM, and his employees acting at his direction, provided dermorphin to trainers for not less than four (4) racehorses that competed in races at racetracks in the Western District of Louisiana. Defendant, Kyle James Hebert, DVM, referred to the dermorphin using the name "1 shot," and advised the horses' trainers that the medication would make the horses focus and run faster. Defendant, Kyle James Hebert, DVM, further told the trainers the medication was "untraceable," meaning that the drug would not be detected in a blood test if such was administered by state

horse racing authorities to determine whether the horse was given the drug prior to entering a race.

5. It was further part of the conspiracy that on race days, defendant, Kyle James Hebert, DVM, and his employees acting at his direction, created or caused to be created a liquid suspension out of powdered dermorphin and loaded it into syringes equipped with hypodermic needles. Contrary to federal law, these syringes either had no label attached to them, or they had only a hand-written "1" on end of the plunger of the syringe, that did not correctly identify the contents of the syringe as being a dermorphin suspension, did not identify defendant, Kyle James Hebert, DVM, as the veterinarian who had supplied the medication, and did not provide instructions for use of the drug.

6. It was further part of the conspiracy that defendant, Kyle James Hebert, DVM, and his employees acting at his direction, provided horse trainers at race tracks with the mislabeled syringes of dermorphin suspension with oral instructions regarding how to inject the drug into the horses, and instructed the trainers to inject an hour before race time. Defendant, Kyle James Hebert, DVM, did this, and caused his employees to do this, in spite of Racing Commission regulations that prohibit possession of a hypodermic syringe at a horseracing track by anyone other than a licensed veterinarian, and regulations that prohibit anyone from injecting horses with any substance within four hours of a post-time, meaning the time that horses gather at the starting post to begin a race, of a race in which the horse will race, and regulations that prohibit administering a race horse any drug not approved by FDA.

7. It was further part of the conspiracy that on some occasions, defendant, Kyle James Hebert, DVM, and his employees acting at his direction, created or caused to be created invoices for his veterinary services that were back-dated in order to conceal the fact that the dermorphin syringes were distributed to trainers on race days. He further created or directed his employees to create invoices for his services that falsely identified the medications supplied as "bleeder supplements" or "joint supplements," knowing instead that he had supplied dermorphin.

8. It was further part of the conspiracy that in 2010 and 2011, defendant, Kyle James Hebert, DVM, hired two other licensed veterinarians to assist him in his practice. Defendant, Kyle James Hebert, DVM, instructed these veterinarians regarding which trainers to supply, how to prepare back-dated invoices for the dermorphin injections using the description "bleeder supplements" or "joint supplements," how to prepare the dermorphin suspensions, how to label the syringes, and what to tell the trainers regarding how and when to inject the dermorphin. Defendant, Kyle James Hebert, DVM, falsely represented to those veterinarians that the dermorphin, which he referred to as "d-peptide," an amino acid that helped the horses "focus." Defendant, Kyle James Hebert, DVM, later instructed those veterinarians on what to say about the "D-peptide" if questioned by the Louisiana Racing Commission or the Louisiana State Police about their distribution of the substance to horse trainers.

OVERT ACTS

E. In order to accomplish the objects of the conspiracy and in attempting to do so, the defendants, Kyle James Hebert, DVM, and Kohll's, d/b/a Essential

Pharmacy Compounding, committed the overt acts described below in furtherance of the conspiracy. Defendant, Kohl's, d/b/a Essential Pharmacy Compounding, shipped dermorphin from Omaha, Nebraska to defendant, Kyle James Hebert, DVM, who received the dermorphin in the Western District of Louisiana on or about the dates, in the quantities, and for payment as described on the table below:

DATE	Number of vials of Dermorphin	Quantity in. Vials	Cost
November 11, 2010	3	1 mg	No Charge
November 17, 2010	3	1 mg	\$150.00
December 2, 2010	2	5 mg	\$360.00
December 13, 2010	5	5 mg	\$690.00
January 4, 2011	10	5 mg	\$1,800.00
February 9, 2011	10	5 mg	\$1,800.00
March 10, 2011	5	5 mg	\$750.00
March 22, 2011	3	5 mg	\$540.00
April 7, 2011	10	5 mg	\$1,500.00
April 28, 2011	5	5 mg	\$750.00
May 12, 2011	20	5 mg	\$3,000.00
June 3, 2011	10	5 mg	\$1,500.00
June 15, 2011	10	5 mg	\$1,500.00
October 19, 2011	10	5 mg	\$1,500.00
November 17, 2011	20	5 mg	\$3,000.00
January 3, 2012	20	5 mg	\$3,000.00
March 1, 2012	10	5 mg	\$1,500.00
May 2, 2012	20	5 mg	\$3,000.00

Counts 2 through 6 of this Indictment are incorporated herein by reference as separate overt acts in furtherance of the conspiracy set forth above, all in violation of Title 18, United States Code, Section 371. [18 U.S.C. § 371].

COUNT 2

**Introduction of Adulterated or Misbranded Drug
in Interstate Commerce, With Intent to Defraud and Mislead**
[21 U.S.C. §§ 331(a) and 333(a)(2)]

On or about March 1, 2012, in the Western District of Louisiana and elsewhere, the defendant, Kohl's, d/b/a Essential Pharmacy Compounding, with the intent to defraud and mislead, introduced and caused to be introduced in interstate commerce, a drug that was adulterated, as defined at 21 U.S.C. §§ 351(a)(5) and 360b, and misbranded, as defined at 21 U.S.C. §§ 352(f)(1), and 352(b) and (f), namely dermorphin, all in violation of Title 21, United States Code, Sections 331(a) and 333 (a)(2). [21 U.S.C. §§ 331(a), 333 (a)(2)].

COUNT 3

**Receipt of Adulterated or Misbranded Drug in Interstate
Commerce, and Delivery or Proffered Delivery thereof**
With Intent to Defraud and Mislead
[21 U.S.C. §§ 331(c) and 333(a)(2)]

On or about March 1, 2012, in the Western District of Louisiana and elsewhere, the defendant, Kyle James Hebert, DVM, with the intent to defraud and mislead, received and caused to be received in interstate commerce, a drug that was adulterated, as defined at 21 U.S.C. §§ 351(a)(5) and 360b, and misbranded, as defined at 21 U.S.C. § 352(f)(1) and U.S.C. § 352 (b) and (f), namely dermorphin, and delivered and caused the delivery and proffered delivery thereof for pay and otherwise, all in violation of Title 21, United States Code, Sections 331(c) and 333 (a)(2). [21 U.S.C. §§ 331(c), 333 (a)(2)].

COUNT 4

**Introduction of a Misbranded Drug in
Interstate Commerce, with Intent to Defraud and Mislead
[21 U.S.C. §§ 331(a) and 333(a)(2)]**

On or about May 2, 2012, in the Western District of Louisiana and elsewhere, the defendant, Kohl's, d/b/a Essential Pharmacy Compounding, with the intent to defraud and mislead, introduced and caused to be introduced in interstate commerce, a drug that was adulterated, as defined at 21 U.S.C. §§ 351(a)(5) and 360b, and misbranded, as defined at 21 U.S.C. § 352(f)(1), and U.S.C. § 352 (b) and (f), namely dermorphin, all in violation of Title 21, United States Code, Sections 331(a) and 333 (a)(2). [21 U.S.C. §§ 331(a), 333 (a)(2)].

COUNT 5

**Receipt of Adulterated or Misbranded Drug in Interstate
Commerce, and Delivery or Proffered Delivery thereof
With Intent to Defraud and Mislead
[21 U.S.C. §§ 331(c) and 333(a)(2)]**

On or about May 2, 2012, in the Western District of Louisiana and elsewhere, the defendant, Kyle J. Hebert, DVM, with the intent to defraud and mislead, received and caused to be received in interstate commerce, a drug that was adulterated, as defined at 21 U.S.C. §§ 351(a)(5) and 360b, and misbranded, as defined at 21 U.S.C. § 352(f)(1) and U.S.C. § 352 (b) and (f), namely dermorphin, and delivered and caused the delivery and proffered delivery thereof for pay and otherwise, all in violation of Title 21, United States Code, Sections 331(c) and 333 (a)(2). [21 U.S.C. §§ 331(c), 333 (a)(2)].

COUNT 6

**Misbranding a Drug While Held for Sale After Shipment
in Interstate Commerce with Intent to Defraud and Mislead
[21 U.S.C. §§ 331(k) and 333(a)(2)]**

Beginning on or about November 11, 2010, and continuing until at least on or about May 12, 2012, within the Western District of Louisiana, the defendant, Kyle James Hebert, DVM, with the intent to defraud and mislead, committed acts, and caused the commission of acts, namely, repackaging and causing the repackaging of the drug dermorphin in syringes equipped with a hypodermic needles with no label or markings on the syringe other than "#1" on the plunger of the syringes, resulting in the drug dermorphin being misbranded, as defined at 21 U.S.C. § 352(f)(1), while held for sale after the dermorphin had been shipped in interstate commerce, from Omaha, Nebraska to the Western District of Louisiana, all in violation of Title 21, United States Code, Sections 331(k), and 333(a)(2). [21 U.S.C. §§ 331(k), 333 (a)(2)].

A TRUE BILL:

REDACTED

FOREPERSON: FEDERAL GRAND JURY

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